6319. Vacuum cleaners. (F.D.C. No. 43519. S. Nos. 64–764/5 P.)

QUANTITY: 16 vacuum cleaners at Durango, Colo., in possession of Floyd Main.

SHIPPED: Between 3–24–59 and 7–9–59, from Amarillo, Tex., and Detroit, Mich.

ACCOMPANYING LABELING: Two printed pages of sales instructions.

LIBELED: 9–9–59, Dist. Colo.

CHARGE: 502(a)—while held for sale, the labeling which accompanied the article contained false and misleading representations that the article would be effective in preventing airborne infections causing 85 percent of deaths from infectious and parasitic diseases; and that it would eliminate many causes of sickness and disease by removing dust from the air in the home; and 502(f)(1)—the labeling of the article failed to bear adequate directions for use for the purposes for which it was intended, namely, in the prevention and treatment of colds, croup, asthma, hay fever, sinus infections, and for the prevention of airborne infections in general, and tuberculosis in particular, which were the purposes for which the article was offered in oral statements made by Floyd Main in promoting the sale of the article.

DISPOSITION: 7–25–60. Consent—claimed by Floyd Main, Durango, Colo., and released under bond to be sold only in compliance with the law.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

DRUGS FOR HUMAN USE

6320. Contact lens wetting solutions. (Inj. No. 387.)

COMPLAINT FOR INJUNCTION FILED: 8–23–60, N. Dist. Ill., against James H. Conover, t/a Micon Laboratories, Chicago, Ill.

LABEL IN PART: "MI-CON Wetting Solution A sterile cleanser for PLASTIC CONTACT LENSES, containing the germicide Benzalkonium Chloride. * * * Active ingredients: Alkyl dimethyl benzyl ammonium chloride 1:25000 MICON LABORATORIES 905 Jackson St. Wauconda, Ill."; "I-SEPTIC A sterile, Isotonic soothing solution for the wetting and cleansing of plastic Corneal Lenses. * * * Active ingredient: Alkyl dimethyl benzyl ammonium chloride, chlorophyll 1:50,000. MICON LABORATORIES 905 Jackson St., Wauconda, Ill."; "STERL-IZE A sterile isotonic supplement to MICON contact lens fluids. * * * Active ingredients: Merthiolate 1:100,000, Dehydroacetic acid sodium salt 0.40%. MICON LABORATORIES Wauconda, Ill."; "STERILEN A sterilizing solution for storing contact lenses STERILIZES . . . As it soaks . As it wets . As it cleans To promote greater comfort and longer wearing time. MICON LABORATORIES 905 Jackson St. Wauconda, Ill. * * * ACTIVE INGREDIENTS: Alkyldimethylbenzyl, Ammonium Chloride 1:10,000 DHA–S—0.4%"; (vial) "5 cc. Sample UCL Wetting Solution Directions * * * Distributed by United Contact Lens Corp. 76 Madison Ave., New York 16, N.Y." and (ctn.) "Pints W S. Micon From Micon Labs. Wauconda, Ill. to United Contact Lenses 76 Madison Ave., New York City."

CHARGE: The complaint alleged that the defendant was engaged in the business of manufacturing, preparing, packaging, labeling, selling, and distributing articles of drug, namely, *"Mi-Con Wetting Solution," "I-Septic," "Sterl-Ize," "Sterilen,"* and *"UCL Wetting Solution,"* and that he had been

and was causing to be introduced and delivered for introduction into interstate commerce, such drugs which were adulterated under 501(c) in that their purity and quality fell below that which they purported and were represented to possess since they purported and were represented to be suitable for use in the eyes and for wetting, cleaning, and storing contact lenses, whereas they were not suitable for such purposes because they were contaminated with large numbers of viable micro-organisms and other foreign material; and, further, that such drugs were misbranded under section 502(a) in that the labeling of the articles contained false and misleading representations that the articles were sterile.

It was alleged further that the adulterated and misbranded condition of such drugs resulted from the presence of foreign material and viable micro-organisms due to inadequate manufacturing facilities, lack of identification control, lack of adequate analysis and formula, lack of qualified personnel, and lack of other precautions essential to the processing and sterilizing of such drugs.

The complaint alleged also that the defendant was well aware that his activities were violative of the Act; that an inspection was made on 4–30–59, at which time the defendant was warned that various articles of drug were not sterile; that an inspection was made on 1–20–60, at which time defendant was warned that questionable procedures were being employed with respect to insuring the sterility of the products; that seizures of *Mi-Con Wetting Solution* and the *UCL Wetting Solution* had been made; and that despite such warnings, the defendant continued to introduce adulterated and misbranded drugs as indicated above.

DISPOSITION: On 8–24–60, the court entered a temporary restraining order, without notice, restraining the defendant against the acts complained of.

On 9–2–60, the defendant having consented, the court entered a permanent injunction enjoining the defendant from directly or indirectly introducing or causing to be introduced and delivering or causing to be delivered for introduction into interstate commerce, drugs, such as *Mi-Con Wetting Solution*, *I-Septic*, *Sterl-Ize*, *Sterilen*, and *UCL Wetting Solution*, or any similar drugs which are represented as suitable for use in the eyes and for wetting, cleaning, and storing contact lenses, that are (a) adulterated in that they contain viable micro-organisms, or other foreign material; and (b) misbranded in that they contain false and misleading representations that they are sterile.

The defendant was further enjoined from directly or indirectly introducing or causing to be introduced or delivering or causing to be delivered for introduction into interstate commerce, any drugs unless and until—

(a) sufficient qualified and experienced personnel, including supervisory personnel, is employed in the plant to properly operate it;

(b) a properly qualified chemist is employed to make sufficient analysis of batches of the finished drug to insure sterility and conformity to the labeling under which it is to be shipped, or other standard which may be applicable. Lacking this, a representative sample of each finished batch of drug is submitted to a reliable, established, outside laboratory for examination prior to shipment;

(c) a sampling of finished products is done in a representative manner to insure the taking of a representative and adequate sample;

(d) the practice of shipping finished batches of drugs prior to analysis or without analysis is discontinued; and

(e) a representative of the Food and Drug Administration, Department of Health, Education, and Welfare, inspects the plant and determines that adequate control systems have been installed as listed herein, and as considered necessary in the manufacturing of ophthalmic products.

6321. Vitamin B_{12} injection. (F.D.C. No. 44485. S. No. 27–407 R.)

QUANTITY: 776 individually ctnd. vials at Minneapolis, Minn., in possession of Ulmer Pharmacal Co.

SHIPPED: 1–13–60, from Decatur, Ill.

LABEL IN PART: (Ctn. and vial) "L.F.B. 12–100 10 cc. For Intramuscular Injection Cat. No. 2185 Each cc. contains: Vitamin B_{12} Activity (From Liver Injection U.S.P. Beef) Equivalent to: Cyanocobalamin 10 mcg. * * * Fortified with: * * * Vit. B_{12} Cryst. 100 mcg. * * * The Ulmer Pharmacal Company, Minneapolis 3, Minnesota."

RESULTS OF INVESTIGATION: Examination showed that the article contained approximately 79 percent of the declared amount of vitamin B_{12}.

LIBELED: 6–8–60, Dist. Minn.

CHARGE: 501(c)—while held for sale, the strength of the article fell below that which it purported to possess; and 502(a)—the unqualified label statement "The Ulmer Pharmacal Company, Minneapolis 3, Minnesota" suggested and implied that the Ulmer Pharmacal Co., was the manufacturer of the article which statement was misleading since the Ulmer Pharmacal Co., was not the manufacturer of the article; and the label statement "Each cc, contains * * * Vitamin B_{12} activity * * * equivalent to * * * Cyanocobalamin 10 mcg." was false and misleading as applied to an article that contained less than the declared amount of vitamin B_{12}.

DISPOSITION: 7–26–60. Default—destruction.

6322. Chorionic gonadotropin injection. (F.D.C. No. 44504. S. No. 8–858 R.)

QUANTITY: 14 pkgs., each containing 1 10-cc. vial of chorionic gonadotropin and 1 10-cc. vial of a diluent at New Hartford, N.Y.

SHIPPED: 4–10–58, from Chicago, Ill.

RESULTS OF INVESTIGATION: Analysis of the article showed that it contained less than 2,500 international units of chorionic gonadotropin potency per vial.

LIBELED: 6–21–60, N. Dist. N.Y.

CHARGE: 501(c)—while held for sale, the strength of the article fell below that which it was represented to possess; and 502(a)—the label statement "Chorionic Gonadotropin 2500 I.U." was false and misleading.

DISPOSITION: 9–14–60. Default—destruction.

DRUGS FOR VETERINARY USE

6323. Veterinary drugs. (F.D.C. No. 44204. S. Nos. 49–689 P, 60–413/4 P.)

QUANTITY: 18 1-lb. cans, 5 10-lb. drums, 1 50-lb. drum, and 2 100-lb. drums, of *Vetrodine* and 16 ctns., each containing 50 boluses (12½ grams), and 24 ctns., each containing 50 boluses (8 grams), of *phenothiazine*, at Portland, Oreg.

SHIPPED: Between 6–26–59 and 12–16–59, from El Cerrito, Calif., by Vetrochem.

LABEL IN PART: (Can or drum) "Vetrodine An Iodine Compound for livestock only * * * Each pound contains: Ethylenediamine Dihydriodide 21